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Ideas. Experience. Practical answers.

**VAPING 2019: LEGAL AND REGULATORY FRAMEWORK
AND RESPONSES TO TWO EPIDEMICS**

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Vaping: December 2019 MD Comptroller



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Terminology and Products

Electronic Smoking Device—ESD (Maryland statutes)

Electronic Nicotine Delivery System—ENDS (Federal regulations)

Electronic cigarette or e-cigarette (CDC)

Closed system v. Tank system

And JUUL . . .

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2018 National Youth Tobacco Survey Data (released 2019)

20.8% of high school students reported ESD use
(up from 11.7% in 2017)

4.5% of middle school students reported ESD use
(up from 3.3% in 2017)

Of student users:

- » 28% used 20 or more days (up from 20%)
- » 68% used flavored ESD (up from 61%)

3.6 MILLION youth use ESD

Now the most commonly used tobacco product by youth.

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Federal Tobacco Laws and Vape

- The Tobacco Control Act (2009) granted FDA authority over the manufacture, marketing and sale of tobacco products.
- The Act directly regulates **cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.**
- FDA authorized to “deem” any **“product made or derived from tobacco that is intended for human use”** as a tobacco product and subject to all or part of the Act.
- On **August 8, 2016** “deemed” anything meeting the statutory definition of a tobacco product, including e-cigarettes as subject to the Tobacco Control Act...

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“Deeming” Rule on Vape Products

Retailers

Ban sale to minors

Must check ID (under age 27)

Ban on vending machine sales

“Deeming” Rule and Vape Products

Vape Product Manufacturers

Register with FDA and provide product listings

Report ingredients and harmful/potentially harmful constituents

Place health warnings on packages and ads

Child resistant packaging

Not sell tobacco products that make modified risk or cessation claims (unless approved by FDA)

And . . .

Pre-Market Tobacco Product Applications

Deeming Rule also imposed:

Pre-market review and market authorization of products entering market after February 15, 2007

Deadline has changed several times:

- Deeming said August 8, 2018 and products could stay on the market for 12 months after application filed.
- 2017 Agency changed to August 8, 2022 and products could stay on the market until application rejected or affirmative order issued.
- 2018 Agency changed to August 8, 2021.
- 2019 Court Ordered May 11, 2020 (12 months on market, or longer if Agency close to determination) – **must address flavors!**

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Public Health Standard for PMTA

FDA must deny a PMTA where it finds
“there is a lack of a showing that
permitting such tobacco product to be
marketed would be appropriate for the
protection of the public health.”

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Modified Risk Tobacco Product Applications

Manufacturer may not make reduced harm claims about a tobacco product without approval from the FDA.

No vape product manufacturers have filed an MRTP application.

— FDA Newsroom

But we know that is what they have been doing subtly, right?

FDA NEWS RELEASE

FDA warns JUUL Labs for marketing unauthorized modified risk tobacco products, including in outreach to youth

Agency sends additional letter requesting more information on several issues, including outreach and marketing practices, as part of ongoing investigation

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For Immediate Release:
September 09, 2019

Today, the U.S. Food and Drug Administration issued a [warning letter](#) to JUUL Labs Inc. for marketing unauthorized modified risk tobacco products by engaging

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Federal Flavor Ban . . .

I thought I'd have something to say here.

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State Flavor Bans/Proposals

Michigan, New York, Rhode Island, Washington, Oregon, Montana: Banned flavored vape products, by emergency declaration/executive order, temporary in nature.

Massachusetts: ALL vapes (done as executive order but pending legislation now)

Several local jurisdictions around the country have banned flavors; SF bans all vape products (eff. 1/1/2020—just survived election challenge); lots under consideration now. . .

Why????

Current Outbreak of Lung Illness or NYTS Data?

According to the CDC as of ~~10/29/19~~ **11/20/2019**:

→ ~~1888~~ **2,290** confirmed or probable cases across 49 states, DC, PR, USVI (not AK)

→ ~~37~~ **47** deaths across 25 states

- Most patients reporting vaping nicotine and THC; some only nicotine.

Recall NYTS data came out late summer as well, showing massive spike in youth vaping.

CDC Recommendations

https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html

Easier to link to this than to try to keep it current!

Recent focus clearly on the THC cartridges and Vitamin E Acetate.

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Questions?

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